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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,172	12/21/2001	Yoichi Takahama	322732000401	2837

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,172	TAKAHAMA ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43,51 and 55-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-43, 51, 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/2004 has been entered. The office action of RCE follows:

Response to Amendment

This is a response to the amendment filed 10/15/04. Claims 31, 36 and 51 have been amended. Claims 44-50 and 52-54 have been canceled. Claims 56 and 57 are added. Claims 31-43, 51 and 55-57 are pending.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

1. Applicant's election with traverse of group I in the reply filed on 04/25/2005. The traverse is based on there is not extra burden for searching all of the claims together.

2. Applicants' argument has been fully considered; claims 36-43, 56-57 are rejoined with elected group I. Claims 31-43, 51, and 56-57 are considered before the examiner.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 31-43, 51, 55-57 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Lavanchy et al. (J. Clinical Laboratory Analysis 1996, Vol. 10, pp. 269-276), Lee et al. (Trasnfusion 1995, Vol. 35, pp. 845-849), Rosa et al. (J. Virol. Methods 1995, Vol. 219, pp.

219-232) and Wang et al. (US patent No. 5,106,726A) on the same ground as stated in the previous office Action.

5. In response to the previous office Action, Applicants traverse the rejection and submit that the reference of Lavanchy et al. was published on September 02, 1996, which is later than the priority date of May 07, 1996 of current application priority date.

6. Applicants' argument has been respectfully reconsidered, however, it is still found unpersuasive because the MEDLINE data base search conducted by the examiner indicates that the reference was published before the date if May 07, 1996 (See attachment). Therefore, the reference is still considered as a prior art unless applicants provide more approval rather than a statement by applicants only.

7. Regarding to the motivation of combinining all cited references and limitations taught by the cited references, Rosa et al. teach that the positive detection results increase to 100% (See section of 3.5 on page 229) by using the synthetic antigen peptides. Rosa further teach that use of short synthetic peptides should be helpful by excluding all amino acid sequences that may be responsible for the low specificity due to cross-reactivity with antibodies directed against other viral proteins (See page 230).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 32, 34 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 32 is unclear and confusing for failing to define whether the genetic recombinant HCV antigen is one structural antigen protein or are more than one HCV antigen proteins because there is an inconsistence in the claim for using a "singular form of an antigen protein followed by a plural form of "proteins". Please clarify.

11. Claim 34 recites the limitation "the synthetic antigen" in claim 31. There is insufficient antecedent basis for this limitation in the claim. Because the synthetic antigens cited in claim 32 are more than one antigens, whereas, the cited "the synthetic antigen" in claim 34 is a singular form. It is not clear whether the cited "synthetic antigen" is the same or different from those synthetic antigens cited in claim 32.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 36-43, 56 and 57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,379,886B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention in current application is an obvious version of claimed invention of UDS patent No. 6,379,886B1.

14. An obviousness-type double-patenting rejection is appropriate where the conflict claims are not identical but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by or would have been obvious over,

the reference claim(s). See, e.g., In re Berg, 14U F.3d 1428, 46 USPQZd 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQZd 2010 (Fed. either anticipated by, 1993); In re Longi, F.2d 887, 225 US/Q 645 (Fed. Cir. 1985).

15. In the instant case, the claims in the current application and issued patent are both directed to diagnostic agents comprising a mixture of more than one kinds of HCV antigens conjugated with carrier proteins immobilized onto a solid phase, wherein the ratio of the carrier protein to HCV antigen peptide is at ratio of about 1-3 to 1:20, the carrier protein is water soluble, and is selected from the from group consisting of polystyrene particle, copolymer latex particle, and erythrocyte and gelatin particle. While the claims in the current application cite to use recombinant antigen and synthetic antigen, US patent ""886B1" does not specify the antigen peptides coated onto the same kind of solid support is a recombinant or a synthetic one(s).

16. Because an HCV antigen can be easily produced by either a recombinant DNA technique or synthetic method since both techniques are well established in the art, the claims in the current application are obvious versions of claims 1-8 of patent "886B1".

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 31-43, 51 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US Patent No. 5,705,330A), Wang et al. (US patent No. 5,106,726A) and Lambert S. (US Patent 5,164,299A).

19. Claimed invention is direct to a diagnostic reagent comprising mixture of HCV structural and non-structural antigen peptides of core, NS3, NS4 and NS5, among which either recombinant antigen or synthetic antigen peptides are conjugated with a carrier protein, preferably BSA as carrier particles and mobilized onto a solid supports, wherein the NS3 antigen

polypeptide is preferably made by a recombinant DNA technique, and other antigen are made as synthetic peptides. The solid particle is selected from group consisting of polystyrene particle, copolymer latex particle, and erythrocyte and gelatin.

20. Shah et al. teach a composition comprising mixed microparticles coated with HCV nonstructural protein HC34, and /or HCV C-100 and/or NS5 (See lines 1-66 on col. 7), wherein the HC34 comprises HCV NS3 and NS4. The microparticles are made by the following material selected from group consisting of a polystyrene, polyethylacrylate, and polypropylene etc. Shah et al. do not teach to use erythrocyte as a solid support. Shah et al. also do not teach to conjugate the synthetic HCV antigen peptides to BSA before they are mobilized onto a solid support.

21. Wang et al. teach a method of detecting HCV infection with a HCV agglutination assay. The method comprises conjugating synthetic HCV peptide antigens of C-100 and core with BSA and then mobilizing the conjugated peptide antigens mixture onto the solid support, such as erythrocyte or gelatin particles, or polystyrene latex particles. They conclude that this conjugated antigen is good for both quantitative and qualitative detection of antibodies to HCV in specimens including serum and biofluid (See example, 3-5 on cols. 35 & 36).

22. Lambert disclose that numerous reagents and procedures in the art teach to conjugate a protein antigen to a carrier molecule via variety functional groups between the protein and molecule, wherein the solid support can be selected wit many materials including latex particle and beads in any size (See column 3-4). He further teaches to use BSA to conjugate hepatitis B antigen and mobilized the conjugated antigen to a solid support. He concludes that the BSA conjugated antigens produce enhanced immune response; especially the mixture of the conjugated and unconjugated antigens in a certain proportions provides an enhanced assay performance (See Abstract, columns 6-8 and claims 1-15).

23. Therefore, it would have been obvious for a person with ordinary skill in the art to Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and to combine the methods taught by Shah et al., Wang et al. and Lambert to establish an diagnostic agent of HCV agglutination assay comprising a mixture of conjugated and non-conjugated recombinant and synthetic HCV antigens in order to produce an enhanced assay performance without unexpected results. Hence, the claimed invention as whole is prima facie obvious absence unexpected results.

24. Regarding to the limitation of "synthetic" antigens, this limitation is considered as a process of making the product. In other word, the method of making the product would not change the structural and functional of claimed same product because applicants in the specification do not particularly pointed out that the claimed synthetic antigen peptides are structurally and functionally different from the product made by a recombinant DNA technique, which it is also cited in the prior art.

25. Regarding to the ration of BSA and antigen peptide, applicants are reminded that the modification of the incubation time for overnight to 1:3 to 1:20 is generally recognized as being within the level of the ordinary skill in the art, In re Rose, 105 USPQ 237 (CCPA 1995) because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the workable ranges involves only routine skill in the art, In re Aller, 105, USPQ 233. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Baoqun Li

Bao Qun Li
07/05/2005